

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 03 November 2011, a proposed amendment in condition for allowance was discussed with Mr. Bruce Kramer, Applicants' attorney, in a telephone interview. Authorization for this examiner's amendment was given in a telephone interview with Mr. Bruce Kramer on 03 November 2011.

The application has been amended as follows:

- Claims 1, 6, 7 and 8 have been amended, as listed below.
- Note: For those claims that are neither amended nor canceled as indicated in this Examiner's Amendment, see the amendment filed by Applicants on 29 September 2011.

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1. (Currently Amended) Please delete the three dots "• • •" recited before "(1)" and before "(1)' - a"

6. (Currently Amended) Please delete the three dots "• • •" recited before "(1)" and before "(1)' - a"

7. (Currently Amended) Please delete "R<sup>1</sup>" and replace with "R<sup>01</sup>"; and please delete "alkyl group or"

8. (Currently Amended) Please delete the three dots "• • •" recited before "(1)" and before "(1)' - a"

### **DETAILED ACTION**

This Office Action details reasons for allowance, and is in response to Applicant's Amendment and Remarks filed on 08 September 2011 in which claims 1 and 6 were amended. This Office Action also is in response to Applicant's Supplemental Amendment and Remarks filed on 29 September 2011 in which claim 8 was amended. The Declaration of Mr. Hiroaki Kaneko, submitted by Applicant on 08 September 2011 under 37 CFR §1.132 is acknowledged and will be further discussed below.

Claim(s) 1 and 6-8 have been amended. Claim(s) 1-9 are in condition for allowance.

### ***Reasons for Allowance & Withdrawn Rejections***

Applicant's amendment and remarks filed 08 September 2011 and 29 September 2011, and Declaration of Mr. Hiroaki Kaneko submitted 08 September 2011, with respect to the rejection of claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over Katsukiyo et al. (US Patent No. 5,733,892) in view of Shigehisa et al. (JP 06-072893), have been fully considered and are persuasive.

Applicant has amended the claims to recite "said hyaluronic acid compound showing a complex elastic modulus of more than 200 Pa with its hydrogel having a concentration of 3 wt%". Applicant's amendment is commensurate in scope with the unexpected results provided in the Declaration of Mr. Hiroaki Kaneko. The Declaration of Mr. Hiroaki Kaneko demonstrated that at 3 wt.%, hyaluronic acid conjugated at the carboxyl group with L- $\alpha$ -dipalmitoylphosphatidyl ethanolamine (i.e. a saturated

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phospholipid) formed a non-viscous liquid. A 1 wt.% concentration of hyaluronic acid conjugated at the carboxyl group with L- $\alpha$ -distearoylphosphatidyl ethanolamine (i.e. also a saturated phospholipid), formed a non-viscous liquid. A 3wt.% concentrated solution of the aforementioned compound formed a hydrogel having an elastic modulus of 47 Pa, i.e. less than the 200 Pa required by the instantly amended claims.

Example 1 of the instant specification demonstrates a 3wt.% concentration of hyaluronic acid conjugated at the carboxyl group with L- $\alpha$ -dioleoylphosphatidyl ethanol amine (i.e. an unsaturated lipid) formed a hydrogel having an elastic modulus of 902 Pa; wherein 10 mol% of the hyaluronic acid was conjugated with the phospholipid. Example 2 of the instant specification also demonstrates a 3wt.% concentration of hyaluronic acid conjugated at the carboxyl group with L- $\alpha$ -dioleoylphosphatidyl ethanol amine formed a hydrogel having an elastic modulus of 902 Pa; wherein 40 mol% of the hyaluronic acid was conjugated with the phospholipid.

Thus, Applicant's claimed compounds forms a hydrogel with unexpectedly superior properties. One having ordinary skill in the art could not have reasonably predicted that a modification to an unsaturated lipid and conjugation to the carboxyl group of hyaluronic acid would have resulted in a compound that forms a hydrogel with such a high elastic modulus at 3 wt.%.

The claim as amended more specifically claims the subject matter disclosed and supported in Applicant's Specification.

The rejection is hereby **withdrawn**.

***Conclusion***

Accordingly, the Examiner's amendment is sufficient to place the application in condition for allowance.

Accordingly, claims 1-9 currently amended are sufficient to place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAHAR SCHMIDTMANN whose telephone number is (571)270-1326. The examiner can normally be reached on Mon-Fri 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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